



F.No.4-3/2023-DMC
Government of Pakistan
Drug Regulatory Authority of Pakistan
(Division of Pharmaceutical Evaluation & Registration)
Data Management Cell (DMC)
داتا منیجمنٹ سیل

Islamabad the 20th April, 2023


Attention: **All Market Authorization / Registration Holders**

Subject: **COMPLIANCE TO THE NOTICE DATED 13-03-2023 WITH REGARDS TO SPECIFICATIONS AND DATA RELATED ACTIVITY IN PIRIMS**

In continuation to the letter of even number dated 27-03-2023 and with reference to the Notice dated 13-03-2023 circulated through the website of DRAP for updating the finished product specification and validated method of testing methods for Non-Pharmacopeial products i.e., Manufacturer / Innovator Specifications. Keeping in view the practical difficulties and requests by PPMA and Pharma Bureau, the Competent Authority has been pleased to grant extension for completion of the subject activity till 9th of June, 2023.

2. All Market Authorization / Registration Holders are required to approach Data Management Cell (DMC) of PE&R Division through email (dmc@dra.gov.pk) to obtain company specific PIRIMS Template Sheet along with Guidance Document to complete the requisite activity within given timeline.

3. This is issued with the approval of CEO DRAP.


(ADIL SAEED)
Deputy Director (PE&R)
DRAP Islamabad

Circulation to all Market Authorization / Registration Holders via Website www.dra.gov.pk

Copy to:

ED Pharma Bureau with request to please ensure compliance.